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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,429	10/20/1999	TOSHIHIRO SHIMIZU	2535USOP	7265

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EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/403,429	Shimizu et al.
Examiner	**Art Unit**
Susan Tran	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 14, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-7, 13, and 18-29* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-7, 13, and 18-29* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time filed 03/14/02, and Preliminary Amendment E filed 03/14/02.

The request filed on 03/14/02 for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/403,429 is acceptable, and an RCE has been established. An action on the RCE follows.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20, 21, 23-26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al. US 5,958,453.

Ohno teaches improved buccal disintegrability formulation comprising active agent, mannitol or erythritol, cellulose, e.g., low-substituted hydroxypropyl cellulose (columns 2-5). The formulation can be compressed into tablet that has dissolution time of about 0.1 to 1.0 minutes (column 6, lines 65-67).

Although Ohno is silent as to the teaching of the degree substituted of the hydroxypropyl group, Ohno recognizes the advantages result in obtaining buccal tablet having dissolution time

within the claimed range. However, it would have been prima facie obvious for one of ordinary skill in the art to, by routine experimentation select a suitable low-substituted hydroxypropyl cellulose to obtain a rapid disintegrate buccal tablet. The expected result would be a buccal dissolution dosage that has long shelf-life, low toxicity, ease of administration even without water, and having fast disintegration in the oral cavity even without water (column 7, lines 3-25).

2. Claims 1-7, 13, 18, 19, 22, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al., in view of Shimizu et al. US 6,299,904 (the examiner relies on the foreign priority date of this patent until the translation is provided, the patentability will be reconsidered).

Although Ohno teaches variety of active agents useful for the gastrointestinal function, Ohno is silent as to the specific active agent claimed by the applicant, e.g., lansoprazole.

Shimizu teaches buccal disintegration formulation comprising low-substituted hydroxypropylcellulose, sugar, and active agent, such as lansoprazole (columns 1-3). The dissolution time of the buccal formulation is from about 5 to about 50 seconds (column 8, lines 1-5). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Ohno's formulation using lansoprazole as an active agent in view of the teaching of Shimizu. The reason for this modification is to obtain a buccal disintegrable solid dosage useful for the treatment of the digestive diseases. The expected result would be a storage stable quick dissolve buccal formulation that can be safely administered orally without water.

3. Claims 1-7, 13, 18, 19, 22, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al., and Shashoua et al. US 5,795,909.

Although Ohno teaches variety of active agents useful for the gastrointestinal function, Ohno is silent as to the specific active agent claimed by the applicant, e.g., lansoprazole.

Shashoua teaches pharmaceutical composition in tablet form comprising active ingredients, e.g., lansoprazole (column 35, lines 4-10). The composition further comprising pharmaceutically acceptable carrier (column 48, lines 22-32). Thus, it would have been obvious for one of ordinary skill in the art to modify Ohno's formulation using lansoprazole as an active agent in view of the teaching of Shashoua. The reason for this modification is to obtain a buccal disintegrable solid dosage useful for the treatment of the digestive diseases. The expected result would be a storage stable quick dissolve buccal formulation that can be safely administered orally without water.

Response to Arguments

4. Applicant's arguments filed 03/14/02 have been fully considered but they are not persuasive.

Applicant argues that Ohno does not teach lansoprazole as active ingredient. Contrary to the applicant's argument, Ohno discloses at column 3, lines 1-15 that no limitation to the pharmaceutically active ingredients to be used, for example, gastrointestinal function conditioning agents, and antacids. Lansoprazole is well known in pharmaceutical art to be useful

for the treatment of digestive function, therefore, it would have been obvious to one of ordinary skill in the art to modify Ohno's gastrointestinal function conditioning agents or antacids. Furthermore, newly submitted generic claims do not include lansoprazole as an active agent.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600